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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,367	08/31/2006	Darin G. Schaeffer	8627-1246 (PA-5595-PCT/US)	8070
48003	7590	06/22/2010	EXAMINER	
BRINKS HOFER GILSON & LIONE/CHICAGO/COOK PO BOX 10395 CHICAGO, IL 60610			DOWE, KATHERINE MARIE	
			ART UNIT	PAPER NUMBER
			3734	
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			06/22/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/591,367	<b>Applicant(s)</b> SCHAEFFER, DARIN G.	
	<b>Examiner</b> KATHERINE M. DOWE	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/31/2006</u> .   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claim 26 recites the limitation "the tube" in line 2. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 16, and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Stevens (US 5,514,108). Regarding claims 1-4, Stevens discloses an elongate flexible catheter tip (Fig 1) comprising a corrugated region located between a proximal tip end (60) and a distal tip end (32). The tip comprises a tube member that defines a lumen (52) throughout the elongate flexible tip body. The distal end (32) is rounded (Fig 1).

Regarding claim 16, the flexible tip comprises polyurethane (col 3, ln 55).

Regarding claims 22-25, the corrugated region may be interpreted as an accordion corrugation, wherein the region comprises a plurality of ridges (40, 42, 44, 46, 48) interspersed with a plurality of grooves (20, 22, 24, 26, 28, 30).

6. Claims 1 and 22-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Elkins et al. (US 6,994,700, hereinafter "Elkins"). Elkins discloses a flexible catheter tip comprising a corrugated region (222) between a proximal tip end and distal tip end, wherein the corrugated region is an accordion corrugation (Figs 16A-B). The corrugated region comprises a plurality of ridges interspersed with a plurality of grooves and the wall thickness of the elongate member is substantially the same throughout the length of the flexible catheter tip (Figs 16A-B). The ridges have an outer diameter that is greater than an outer diameter of the tube member extending from the corrugated region (Figs 16A-B). The grooves have an inner diameter that is smaller than the inner diameter of the tube member extending from the corrugated region in the contracted configuration (Fig 16B). The grooves have an inner diameter that is substantially the same as the inner diameter of the tube member extending from the corrugated region in the elongated configuration (Fig 16A).

7. Claims 1 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. (US 5,437,288, hereinafter "Schwartz"). Schwartz discloses a flexible catheter tip comprising a corrugated region between a proximal tip end and distal tip end, wherein the corrugated region is helical (Fig 8).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 5-7, 11, 13-15, and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijay et al. (WO 89/02763, hereinafter "Wijay") in view of Stevens (US 5,514,108). Regarding claim 5, Wijay discloses the invention substantially as claimed including a flexible tip (T), wherein the proximal tip end is adjacently attached to an inner distal end of a dilation catheter (Fig 1). The dilation catheter comprises an elongate outer body (B), an elongate inner body (I), and a balloon (D). The inner body (I) has a proximal region (20) located within the outer body (B) and extends between the proximal and distal ends of the outer body (B). The inner body (I) has a distal region extending past the distal end (62) of the outer body (B). The balloon (D) comprises a proximal balloon leg attached to the distal end of the outer body (B) and a distal balloon leg attached to a distal end of the dilation catheter. A balloon cavity (24) defined by the proximal and distal balloon legs is in fluid communication with the outer lumen (pg 11, ll 20-34).

However, Wijay does not disclose the flexible tip (T) comprises a corrugated region. Stevens discloses a flexible tip (Fig 1), wherein the flexibility of the tip is achieved by forming a plurality of ridges (40, 42, 44, 46, and 48) interspersed with a plurality of grooves (20, 22, 24, 26, 28, and 30) in a corrugated pattern. Stevens teaches the corrugated design gradually varies the rigidity along the length of the tip to provide an improved flexible tip (col 1, ll 31-37; 2, ll 48-64). Therefore, it would have been obvious to one having ordinary skill in the art at the time the

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invention was made to modify the device of Wijay set that the flexible tip was corrugated to ensure the tip portion was sufficiently flexible to prevent damage to the vessel as the catheter is directed through the vasculature.

Regarding claim 6, the proximal tip end is attached to the distal end of the inner body (I) at a tip end attachment (34) and the distal balloon leg (32) is attached across the tip-end attachment (Fig 1). The distal tip end is rounded (Fig 1).

Regarding claim 7, the distal balloon leg (32) may be attached to the distal region proximal to the tip-end attachment (Fig 2).

Regarding claims 11 and 19, the distal balloon leg (32) is attached to the inner distal end (I) providing a distal bonding region, wherein the bonding region has a distal face circumscribing the inner distal end and the proximal tip end (T) is attached to the distal body end via the distal face (Fig 1).

Regarding claims 13 and 14, the distal balloon leg (32) is attached to the distal region, such that the distal region extends beyond the balloon leg and comprises an external mounting shoulder about which the flexible tip (T) is attached (Fig 2).

Regarding claim 15, a tip lumen (14) is defined by the flexible tip (T), wherein the lumen is aligned with a wire guide lumen (12). The wire guide lumen (12) and inflation lumen (A/24) are parallel (Fig 1).

Regarding claims 17 and 18, the proximal tip end (T) is adjacently attached to the distal body end forming a tip-end attachment (34); the distal balloon leg (32) is adjacently attached to the distal body end, the proximal tip end, and the tip-end attachment; and the distal tip (T) is integral with a rounded distal end (Fig 1).

Regarding claims 20 and 21, the distal balloon leg (32) is adjacently attached to the distal body end, forming an external mounting shoulder. The proximal tip end (T) is adjacently

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attached to the distal body end and the distal balloon leg via the external mounting shoulder (Fig 2).

11. Claims 8-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijay (WO 89/02763) and Stevens (US 5,514,108), as applied to claim 5 above, further in view of Crocker (US 5,542,926). Regarding claims 8, 9, and 12, Wijay and Stevens disclose the invention substantially as claimed as shown above. However, Wijay does not disclose the elongated inner body comprises a braided coil reinforcing member. Crocker discloses a similar catheter comprising an elongate body (50) and teaches the body is reinforced by embedding a braided material or coil (51) within body (Fig 6; col 8, ll 5-18). The coil comprises a high strength material such as stainless steel or platinum wire, thus the inner body has a lower durometer than the inner coil material (col 8, ll 5-18). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Wijay such that a coil of higher durometer material was embedded within the inner body to reinforce the column strength of the inner member and improve the pushability of the catheter.

Regarding claim 10, Crocker teaches the coil may be tightly wound or loosely wound depending on the desired flexibility (col 8, ll 25-35). Therefore, it would have been obvious to modify the combination of Wijay, Stevens, and Crocker such that the braided coil was of varying tightness throughout the inner body to vary the flexibility of the inner body as desired.

### ***Conclusion***

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe  
June 18, 2010

/K. M. D./  
Examiner, Art Unit 3734

/Anh Tuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
6/21/10